INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 84 (2015) 229–236

journal homepage: www.ijmijournal.com

# Routinisation of informed consent in online health care systems

*Thomas Ploug*[a,*], *Søren Holm*[b,c,d]

[a] *Aalborg University Copenhagen, Centre for Applied Ethics and Philosophy of Science, Department of Communication, A. C. Meyers Vænge 15, 2450 Copenhagen SV, Denmark*
[b] *University of Manchester, Centre for Social Ethics and Policy, School of Law, Manchester M13 9PL, United Kingdom*
[c] *Center for Medical Ethics, Faculty of Medicine, University of Oslo, Oslo, Norway*
[d] *Department of Health Science and Technology, Aalborg University, Aalborg, Denmark*

ARTICLE INFO

*Article history:*
Received 5 February 2014
Received in revised form
7 January 2015
Accepted 8 January 2015

*Keywords:*
Informed consent
Routinisation
Online health care systems

ABSTRACT

*Objectives:* To investigate (1) the extent to which informed consent is routinised, i.e., given habitually and without reflection, in relation to the use of web-portals containing personal health information, and (2) the reasons given by users for routinised and non-routinised consent behaviour.

*Design:* Anonymous web-questionnaire among users of the official Danish health information web-portal, Sundhed.dk.

*Setting:* Sundhed.dk allows Danish residents access to their electronic patient records and other personal health information and allows them to update some of this information. Use of the portal requires explicit consent to the terms and conditions of use and the data protection policies of the site.

*Main outcome measures:* Degree to which information materials are read before use of the portal.

Reasons given for reading or not reading materials.

*Result:* Seventy-nine percent of respondents read half or less of the information materials before using the portal. The main reasons given for not reading (all) of the materials relate to the length of the materials, the frequency of having to read such things, and the perception that use of the portal is 'low risk'. The reasons given for reading and not reading indicate that the consent process is routinised.

*Conclusions:* Most users of Sundhed.dk do not provide informed consent before using the portal, since most do not read the information fully.

The reasons given for not reading strongly supports the idea that consent has become a routinised behaviour in this context.

This finding is important because web-portals offering access to personal health information held by the health care system are becoming ever more frequent.



* *Corresponding author*. Tel.: +45 31417140.
E-mail addresses: ploug@hum.aau.dk (T. Ploug), soren.holm@manchester.ac.uk (S. Holm).

http://dx.doi.org/10.1016/j.ijmedinf.2015.01.003
1386-5056/

## 1. Introduction

In recent years a National Health IT system has been established in Denmark with a publically accessible web-portal, 'sundhed.dk'. Apart from offering information on various illnesses and the services of the Danish health service, the portal also provides all Danish residents with: (1) access to their personal electronic patient record, (2) a record of prescribed medication, (3) opportunities for booking an appointment with a GP, (4) the possibility to issue an advance directive for lifesaving treatment, (5) the possibility to opt-in to organ or whole body donation, and (6) the possibility to add information to the medication record. The user can also see if health care personnel have accessed their health information. In short, the portal collects, stores, combines and disseminates personal and sensitive health information, and this raises ethical and legal issues [1]. Before accessing personal health information, all users are explicitly required to consent to the collecting, storing and dissemination of information. The consent form for sundhed.dk is less than two pages long (578 words), so it should be readable in less than five minutes. If prospective users do not consent they cannot get access to the site, and cannot use any of its functionalities. Users must consent to the content of the consent form, but they do not need to state that they have actually read the form.

A valid consent requires adequate knowledge and understanding of what is consented to. We have, however, in previous studies shown that across a wide selection of internet services few people read the information provided and the consent is provided as an 'act of routine' [2,3]. The present questionnaire study focuses on the use of the Danish National Health IT portal and investigates the extent and causes of routinisation of consent.

### 1.1. *Personal autonomy, informed consent and routinisation*

Informed consent is key to the protection of personal autonomy in health care as elsewhere [4,5]. Personal autonomy may for present purposes be defined as the ability of a person to form and act upon his or her own reasons and purposes without the controlling influence of others [6–9]. A valid informed consent may be defined as consent obtained (1) from a competent person (2) on the basis of having provided adequate information in ways conducive to the understanding of the implications of the intervention for the person's reasons and purposes, and (3) without having coerced, manipulated or in any other way having unduly influenced the person's choice [10–12]. The practice of seeking valid informed consent protects personal autonomy by providing an individual with an opportunity to reflect, form and act upon his or her own reasons and purposes on the basis of being informed about a potential intervention.

The act of consenting to the collecting, storing and dissemination of personal and sensitive health information carries particular ethical and legal significance [13,14]. The loss of control over access to personal health information – through breaches of security or simply because of legislation providing many and large groups of health personnel with access – may cause harm to the individual in various ways. It may cause negative emotional reactions and it may also influence a person's ability to direct his or her future due to reactions to the information by others, i.e., it may have various discriminatory and stigmatisating effects [15–17]. Finally, the act of consenting also implies a redefinition of legal rights. The legal standing of a person comes to be defined by the conditions set out in the consent form [18].

The previous considerations underscore the importance of securing a valid consent to the collecting, storing and dissemination of personal and sensitive health information. However, the ICT context is characterised by very often requiring users to consent before getting access to applications or internet services of various kinds. The frequent requirement of consent may lead to routinisation. The provision or refusal of consent has been routinised if, and only if, the provision or refusal happens as an unreflective, habitual act [19]. This conception of routinisation is narrower than the conception provided by Betsch et al. who defines a routine as: "An option that comes to mind as a solution when the decision maker recognises a particular decision problem" [20]. In our view it is not sufficient for routinisation that a decision making option simply "comes to mind". Routinisation requires that the decision making option that comes to mind as a solution significantly influences the decision by making it less likely that the decision maker reflects properly on the decision and the decision making context in particular. Our conception of routinisation also differs from the standard conception of habit by focusing on the suspension of reflection on the context of the decision and not merely on the response being more or less automatic [21]. In our view it is not necessary for routinisation that a decision is an automatic response. A person may thus be able to give reasons for responding in a certain way in a given context, but if decision making based on these reasons entails potentially ignoring important features of the context, then it will still count as routinisation in our sense. Routinisation in this sense threatens the protection of personal autonomy through informed consent. The requirement of informed consent is meant to provide a person with the opportunity to reflect on the implications of providing or refusing consent. Routinisation by definition implies the suspension of reflection.

Routinisation may show itself in various ways. First of all, it may show itself in the extent to which the conditions of consent and the policies for protection of privacy are read. Failure to read these indicates routinisation, and *ceteris paribus* the more is read the less the extent of routinisation. Moreover, routinisation also shows itself in the reasons for reading and not reading these conditions and policies. If a person fails to read conditions and policies because they are 'just an obstacle to be overcome', then this seems to imply a stronger degree of suspension of reflection on the implications of providing consent than if the reason for not reading is simply previous 'good experiences' with the relevant party. Similarly, if a person reads the relevant conditions and policies because the 'text appears' then this seems to be indicative of a stronger degree of routinisation than if the person reads because 'the act of consenting is of great importance'. In all these cases the relevant person may reflect on the implications of providing consent, but we take there to be a difference in the degree to